## **Novartis Pharmaceuticals Corporation**

## 59 Route 10

East Hanover, NJ 07936

Appendix 8:
Patient Information Form
(Bisphosphonates and ONJ)

Zometa® (zoledronic acid) Injection

and

Aredia® (pamidronate disodium) Injection

Submitted: February 1, 2005

Oncologic Drugs Advisory Committee Meeting

March 4, 2005

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Patient Demo	ogra	phics								
Date of Birth:										
Date of Birth.		day		month		year		Age		
Gender:		□Male	l		☐ Female					
Adverse Event Report:										
Drug Informa	ation									
Drug Name	Th	herapy Dates		Indication(s)	Dosing at time of eve			ent		
	Fro	om	То				Dose	Formulation		Frequency
Aredia										
Zometa										
				l l						
		Name/	Title:							
Oral Surgeor Dentist:	n/	Address:								
		Telephone:								
		Name/Title:								
Oncologist:		Address:								
		Telephone:								
Other		Name/Title:								
		Addres	SS:							
Healthcare Professional:	:									
		Telephone:								

General Medical History / Medical Conditions / Medical Procedures								
List relevant medical history, medical conditions, and medical procedures with special attention to the following (use page 4 for dental history and page 6 for cancer history):								
Vascular disorders (e.g., injury, vessel compression)	□No □Ye	s (specif	y below)					
Coagulation disorders (e.g, DVT, embolism, hemophilia	)	□No □Ye	s (specif	y below)				
Metabolic / Endocrine disorders (including Diabetes)		□No □Ye	s (specif	y below)				
Alcoholism		□No □Ye	s (specif	y below)				
Anemia		□No □Ye	s (specif	y below)				
Asthma / Lung Disease		□No □Ye	s (specif	y below)				
Autoimmune / Rheumatoid Disease		□No □Ye	s (specif	y below)				
Smoking		□No □Ye	s (specif	y below)				
Chronic Renal Failure		□No □Ye	s (specif	v below)				
History / Condition / Procedure	Date		On	going blem?				
			Yes	s No				
			Ye	s No				
			Ye	s No				
			Yes	s No				
			Yes	s No				
			Yes	s No				
			Yes	s No				
			Yes	s No				
			Yes	s No				

'Background' Medications – Including Bisphosphonate Use							
(within 24 Months prior to diagnosis of Osteonecrosis)							
List medications with special attention to the following (use page 5 for dental medications and page 7 for oncology medications):							
Corticosteroids	[	□No □Yes (specify below	<i>'</i> )				
Pamidronate / Aredia®	[	□No □Yes (specify below	<b>'</b> )				
Zoledronic acid / Zometa	a <sup>®</sup> [	□No □Yes (specify below	<i>'</i> )				
Other Bisphosphonates	[	□No □Yes (specify below	/)	T			
Medication	Dose & Regimen	Indication	Date Started	Date Stopped			

Dental History / Dental Conditions							
Please list relevant dental history and dental conditions with special attention to the following:							
Dental conditions (e.g., dental & sinus infections, mucositis,oral complications due to chemotherapy)  □No □Yes (specify below)							
Dental Procedures (e.g., dental extractions, maxillofacial surgeries  □No □Yes (specify below))							
History of trauma or fractures of the Jaw (include trauma due to dental bridgework, dentures, etc.)  □No □Yes (specify below)							
History / Medical condition	Date of Diagnosis / Procedure	Ong prob					
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				
		Yes	No				

Appendix 8

			T				
						Yes	No
Osteonecrosis of the Jaw: Diagnosis & Treatment (if multiple dates of diagnosis are present, this page may be photocopied for additional use)							
Diagnosis (type of		are present, this	s page may be pri	otocopie	u ioi addillor	iai use,	)
osteonecrosis)							
Date of Diagnosis							
Anatomical Site(s)							
Concurrent Factors							
(e.g., tooth extraction, other dental procedures)	er						
		☐ Clinical					
		☐ Imaging (specify)					
Method of Diagnosis		☐ Biopsy (specify)					
		☐ Other (specify)					
Treatment							
Date(s) of Treatment							
Outcome		☐ Resolved (space of the control of	· · · · · · · · · · · · · · · · · · ·	own			
			gg				
	D	ental Medicatio	ns & Treatments	3			
Please list current dental r	medicatio	n/treatments wit	h special attention	n to the fo	ollowing.		
Use of anesthetics in dental		on/treatments with special attention to the following: dures (especially those with □No □Yes (specify below)					w)
vasoconstrictors)	a. p. 000u	a. so (copodially		_110	_ 100 (0000)	., 5010	,
Antibiotics				□No [	⊐Yes (speci	fy belov	w)
Medication/Treatment	Dose & Regimen Indication Date Started Started					<u> </u>	
Medication/Treatment	DOSE &	Regimen	Indication		Started	Stop	ped

Cancer Diagnosis								
Туре	Date o	f Diagnosis						
	Radiation Therapy							
□None □Yes (specify	below)							
Location	Dose & Regimen	Indication	Date Started	Date Stopped				

Oncology Medications								
(within 24 Months prior to diagnosis of Osteonecrosis)  List oncology medications with special attention to the following:								
Chemotherapy								
Corticosteroids   No   Yes (specify below)								
Medication	Dose & Regimen	Indication	Date Started	Date Stopped				
	Healthcare Professiona	al reporter information	on					
Name Specialty								
Signature	Date							
Propared by								